UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,053	11/14/2003	William N. Borkan	829/36582D	9020

7590 05/04/2006

BARNES &THORNBURG
Suite 900
750 17th Street, N.W.
Washington, DC 20006

EXAMINER	
GEDEON, BRIAN T	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,053	BORKAN, WILLIAM N.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *4-6,9,10,16-18 and 21-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/14/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 11-22, 25, 28-35, 38, 41, and 44-46 of U.S. Patent No. 6,510,347. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and instant application recite structure for a stimulating lead having a sheath with a distal end and proximal end, containing a passage extending from an inlet at the proximal end to and outlet at the distal end. Specifics regarding locations of electrodes near the distal end of the stimulating lead are also recited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 7, 8, 14, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deletis et al (US Patent no. 5,081,990) in view of Hess et al. (US Patent no. 4,800,898).

In regards to claims 1, 14, and 19, Deletis et al. presents a catheter for spinal epidural injection of drugs and measurement of evoked potentials. The catheter inherently possesses a distal end and a proximal end, as depicted in figure 1. The distal end has a plurality of electrodes 12, 13, and 14. Passage 31 is adapted to be fitted with a stylet to aid in directing the device for optimal placement, col 3 lines 43-45. The catheter includes another passage 32 located at the proximal end and leads to one or more outlets 11, col 3 lines 49-53, for dispensing medication. Relocation of outlets 11 along the catheter, to the distal end, would be obvious to one of ordinary skill in the art since it has been held that rearranging parts of the involves only routine skill in the art, *In re Japiske*, 86 USPQ 70. Deletis et al. does not show the use of an anchoring element to fixate the device either. Hess et al. discloses a neural stimulator electrode with lead two flexible tine members 44 and 46 to stabilize the lead near the desired location. Therefore it would have been obvious to one of ordinary skill in the art at the

time the invention was made to embody a catheter in this manner so provide electrical and pharmacological therapy to a desired area of the spinal cord.

In regards to claim 2, Deletis et al. describes the invention as claimed except for the fixation means. Hess et al. describes a neural stimulator electrode and lead with two flexible tine members 44 and 46 for fixation of the lead near the desired space, col 4 lines 58-67. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a fixing element on an implantable lead in order to prevent unwanted movement.

In regards to claims 7 and 8, Deletis et al. describes another set of electrodes, 42, 44, and 46, which are different from the electrodes located near the distal end of the catheter. However, does not make any suggestion for a difference in size between the two groups of electrodes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the size of electrode surface area, since factors including material properties and/or electrical properties dictate the appropriate design of surface area, and it would involve only routine skill in the art to make such adjustments.

4. Claims 3, 15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deletis et al (US Patent no. 5,081,990) in view of Hess et al. (US Patent no. 4,800,898), further in view of Vaiani et al. (US Patent no. 5,374,285).

Deletis et al. in view of Hess et al. substantially describe the claimed invention, including the placement of several outlets 11 on the catheter for drug administration, col 3 lines 49-53. However, the outlets 11 are not located at the distal end of the catheter,

Vaiani et al. describes a spinal catheter in which the distal end 1a has been pierced with holes 15 so as to permit drug release into the region surrounding the catheter. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the outlets near the distal end since it has been held that rearranging parts of the involves only routine skill in the art, *In re Japiske*, 86 USPQ 70.

Allowable Subject Matter

5. Claims 4-6, 9, 10, 16-18, and 21-23, objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. EP 1 502 624 A1, EP 1181 948 A2, EP 1 181 947 A2, and EP 1 180 380 A2 all to Borkan, which describe a neurostimulation lead for implantation in the intrathecal space disclosing the same features of the current invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3766

BTG